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IS 13523-2 (1992): Medical electrical equipment - Shortwave therapy equipment, Part 2: Performance requirements [MHD 19: Immuno-Biological Diagnostic Kits]



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भारतीय मानक

चिकित्सीय विद्युत उपकरण — लघु तरंग उपचार उपकरण

भाग 2 कार्यकारिता अपेक्षाएँ

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT —
SHORT-WAVE THERAPY EQUIPMENT

PART 2 PERFORMANCE REQUIREMENTS

UDC 615.471 : 621.31

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BUREAU OF INDIAN STANDARDS
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FOREWORD

This Indian Standard (Part 2) was adopted by the Bureau of Indian Standards, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard is being issued in two parts. Part 1 covers General and safety requirements, and Part 2 Performance requirements.

The short wave therapy equipment is a special type of electromedical equipment. The rf output power used depends largely on the subjective reaction of the patient. Any relative indication must not be confusing to the user.

Safety hazards tend to increase with the output power. A power of 500 W is considered sufficient for normal treatment (except possibly for whole-body heating) and is recommended.

Reducing the output power merely by detuning the output circuit would be hazardous as the movement of the patient could change the tuning and increase the power thereby.

Energization of the generator only at the minimum setting of the output control prevents a patient from being treated inadvertently at an excessively high setting of this control. Also, short-wave therapy is often performed without continuous supervision. Therefore, a timer for switching off is essential. In actuating parts of controls, a non-conductive cord avoids the risk of rf burns.

In the preparation of this standard, assistance has been derived from IEC 601-2-3 (1982) 'Medical electrical equipment — Part 2 : Particular requirements for the safety of short-wave therapy equipment', issued by the International Electrotechnical Commission (IEC).

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT — SHORT-WAVE THERAPY EQUIPMENT

PART 2 PERFORMANCE REQUIREMENTS

1 SCOPE

This standard (Part 2) specifies performance requirements of short-wave therapy equipment.

2 REFERENCES

The following Indian Standards are necessary adjuncts to this standard:

IS No.	Title
325 : 1978	Three-phase induction motors (<i>fourth revision</i>)
996 : 1979	Single-phase small ac and universal electric motors (<i>second revision</i>)
13450 (Part 1) : 1992	Medical electrical equipment : Part 1 General requirements for safety (<i>under print</i>)

3 TERMINOLOGY

3.1 For the purpose of this standard the definitions given in Part 1 of this standard shall apply.

4 ACCURACY OF OPERATING DATA

4.1 Any incorporated means for the relative indication of output power shall not display numerical values which may be confused with actual output power.

4.1.1 Compliance shall be checked by inspection.

4.2 The maximum output power of the equipment when measured as described below shall not deviate from the rated output power by more than ± 20 percent.

NOTE — An accuracy of ± 20 percent is considered adequate for this kind of equipment. The measuring method using a resistive load is chosen as it allows the use of different resistance values and gives better measuring accuracy than a lamp load. It has been found practicable to couple an inductive applicator to this load by means of a resonant circuit,

4.2.1 Compliance shall be checked by measurement of the output power.

4.2.2 For equipment having a rated output power not exceeding 25 W, the measurement shall be made as specified by the manufacturer.

4.2.3 For other equipment, the following test methods shall apply.

4.2.3.1 *Capacitive applicators*

The measurement is made using a resistive load, normally 50 Ω to 150 Ω which is electrically balanced with respect to earth at the operating frequency (*see* Fig. 1).

The error of the power measuring device shall not exceed ± 5 percent. Diameters of metal plates in Fig. 1 may be increased when the applicators have diameters greater than 170 mm.

The spacing between the applicators and the metal plates of the load is varied so as to maximize the power output into a given load resistance. The test is repeated with different values of load resistance and all capacitive applicators specified for use with the equipment. The maximum value of power output measured shall fulfil the above requirement.

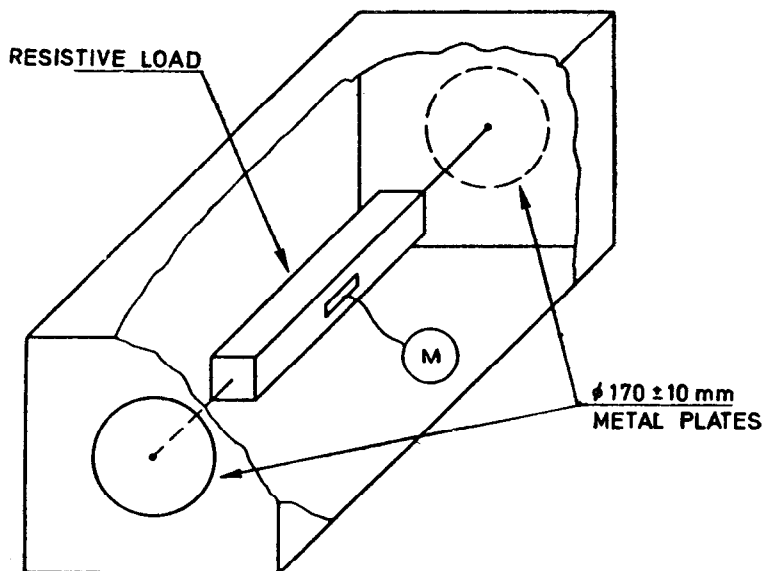
4.2.3.2 *Inductive applicators*

For inductive applicators, coupling to the load may be achieved using a resonant secondary circuit. Alternatively, a calorimetric method using 0.9 percent saline solution or other materials may be used.

NOTE — Details of this test are under consideration.

5 PROTECTION AGAINST INCORRECT OUTPUT

5.1 If the control range of equipment is such that the delivered output in a part of the range is considerably greater than the output which is regarded as a safe limit, means shall be provided which prevent such a setting or which indicate to the operator (for example, by



NOTE — The diameter of the metal plates may be increased when the applicators of the equipment under test have diameters greater than 170 mm.

FIG. 1 POWER MEASURING DEVICE

means of an apparent additional resistance when the control is set or the bypassing of an interlock or by an additional special or audible signal) that the selected setting is in excess of a safety limit.

5.2 The rated output power of the equipment shall not exceed 500 W.

5.2.1 Compliance shall be checked by comparison of the rated output power with the value measured in the compliance test of 4.2.

5.3 Equipment containing components having a limited reliability, for example, semiconductors which control currents in patient circuits, shall be investigated to establish the effects of their failure to operate in the intended manner, including any additional failure caused by this, in particular, concerning the output of the patient circuit.

In other respects, the equipment shall satisfy the relevant requirements of IS 13450 (Part 1) : 1992.

5.4 Where the equipment is a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments, appropriate steps shall be taken to minimize the possibility of a high intensity output being selected accidentally.

This may be achieved, for example, by providing separate output connections or by the

provision of a separate manually operated interlocking device.

5.5 The equipment shall incorporate means (an output control) to enable the output power to be reduced to less than 50 W or 20 percent of the rated output power whichever is lower, other than by detuning of the output circuit.

NOTE — Reducing the output power merely by detuning the output circuit would be hazardous as the movement of the patient could change the tuning thereby increasing the power.

5.5.1 Compliance shall be checked by inspection and by measurement of the output power using the method given in 4.2.

5.6 The equipment shall be so designed that the output circuit is not energized unless the output control is first set to the minimum position.

This requirement shall also be met after the interruption and restoration of the main supply.

5.6.1 Compliance shall be checked by a functional test.

5.7 Equipment shall be provided with an adjustable timer which de-energizes the output circuit when a pre-selected operating period has elapsed.

5.7.1 Compliance shall be checked by inspection and a functional check.

6 FAULT CONDITIONS CAUSING OVER-HEATING AND/OR MECHANICAL DAMAGE — ENVIRONMENTAL TESTS

6.1 Equipment shall be so designed that the risk of overheating and mechanical damage related to safety or electric shock as a result of fault conditions is obviated as far as is practicable. The test method is given in Annex A. However, the following cases are excluded from the tests:

- a) Motors, the supply circuits of which limit the energy which may be dissipated in the motor under mechanical overload conditions;
- b) Motors enclosed in fire-proof enclosures;
- c) Motors provided with inherent thermal or overcurrent protection;
- d) Synchronous timing motors and totally enclosed permanent magnet motors; and

e) Position repeater motors, stepping motors, pen motors.

6.2 Equipment should be so designed that in the case of a short circuit in any output circuit which is unprotected, no hazard exists for the patient or user, or to the surroundings.

6.3 The functioning of an overload protective device as part of the equipment shall not result in a fire, electric shock or accident hazard.

7 CONSTRUCTIONAL REQUIREMENTS

7.1 Relevant provision of IS 13450 (Part 1) : 1992 shall apply except as given in 7.2 and 7.3.

7.2 Where a patient operated switch is incorporated to de-energize the output, such a switch shall be operated via a non-conductive cord to prevent the risk of rf burn.

7.3 Neutral electrode connected to the patient shall have sufficient area of contact on the body allowing a return path of high frequency current with such a low current density in the body tissue as to avoid burns, specially with children.

ANNEX A

(Clause 6.1)

TEST FOR CHECKING FAULT CONDITIONS

A-1 Equipment having heating elements shall be checked for compliance as follows:

- a) For thermostatically controlled equipment which is intended for building-in or for unattended operation, or which has a capacitor not protected by a fuse or other similar device connected in parallel with the contacts of the thermostat : by the test of A-3 and, if necessary, by the test of A-4 followed by the test of A-5;
- b) For equipment having heating elements with short time rating : by the test of A-3 and if necessary, by the test of A-4 followed by the test of A-6 ;
- c) For other equipment having heating elements : by the test of A-3 and, if necessary, by the test of A-4 ; and
- d) For Class II equipment, the test of A-5 is made on all equipment incorporating a thermostat or other thermal control.

If more than one test is applicable to the same

equipment, the tests shall be performed consecutively.

If, in any of the tests, a non-self-resetting thermal cut-out operates, a heating element or an intentionally weak part ruptures, or if the current is otherwise interrupted without the possibility of automatic restoration before steady conditions are established, the heating period is considered to be over. However, if the interruption is due to the rupture of a heating element or of an intentionally weak part, the test is repeated on a second sample. Open circuiting of a heating element or of an intentionally weak part in the second sample will not in itself entail a rejection. Both samples shall comply with the conditions specified in A-6.

Fuses, thermal cut-outs, over-current releases or other similar devices incorporated in the equipment, may be used to provide the necessary protection against risk of fire.

A-2 Equipment having motors shall be checked for satisfactory and safe operation. The motors shall generally comply with the requirements of relevant Indian Standards (see IS 996 : 1979 and IS 325 : 1978).

A-3 The heating parts of equipment are tested under the conditions specified in IS 13450 (Part 1) : 1992 but without adequate heat discharge (with impaired cooling), the supply voltage being such that the input power is 0.85 times the rated input power.

Conditions with adequate heat discharge (with impaired cooling) shall be described in the relevant standards.

If a non-self-resetting thermal cut-out operates, or if the current is otherwise interrupted without the possibility of automatic restoration before steady thermal conditions are established, the operating period is considered to be over and the test of **A-4** is not made. If interruption of the current does not occur, the equipment is switched off as soon as steady thermal conditions are established, and is allowed to cool down to approximately room temperature. The equipment is then subjected to the test of **A-4**.

For equipment with short time rating, the duration of the test is equal to the rated operating time.

A-4 The test of **A-3** is repeated, but with a supply voltage such that the input power is 1.24 times the rated input power. In case of doubt, a test is made with the least favourable supply voltage between the limits specified in **A-3** and this clause.

A-5 The test of **A-4** is repeated, but with the equipment operated in accordance with the conditions of adequate heat discharge and with any control which serves to limit the temperature under short-circuited conditions.

If the equipment is provided with more than one thermostat or temperature switch, these are short-circuited in turn.

A-6 The test of **A-4** is repeated, but with the equipment operated in accordance with the conditions of adequate heat discharge until steady thermal conditions are established, irrespective of the rated operating time.

For this test, the thermostats are not short-circuited.

A-7 Equipment rated for short time or intermittent operation other than a) hand-held

equipment, b) equipment which has to be kept switched on by hand, c) equipment which is continuously loaded by hand, and d) equipment with a timer shall withstand the effects of continuous operation, that is, by operating the equipment under normal load and at rated voltage or at the upper limit of the rated voltage range until steady thermal conditions are established, or until the protective device operates.

A-8 During the test of **A-3** to **A-7**, the equipment shall not emit flames or molten metal, poisonous or ignitable gas in hazardous amounts and enclosures shall not deform to such an extent as to impair compliance with this standard and temperatures of various parts shall not exceed the maximum values shown in Table 1 for an ambient temperature of $25 \pm 2^\circ\text{C}$.

After the tests, the insulation between the mains part and the body of the equipment when cooled down to approximately room temperature shall withstand the dielectric strength test specified in IS 13450 (Part 1) : 1992.

For supplementary and reinforced insulation of thermoplastic materials, the ball pressure test specified in IS 13450 (Part 1) : 1992 is made at the temperature measured during this test, increased by 25°C .

For equipment which is immersed in, or filled with conducting liquid in normal use, the sample is immersed in, or filled with the conducting liquid or water, as appropriate, for 24 hours before the dielectric strength test is made.

A-9 During the tests of this section, thermostats, thermal cut-outs and overload releases shall be inspected to establish that their setting has not changed appreciably by heating, vibration or other causes.

Table 1 Maximum Temperature Under Fault Conditions
(Clause A-8)

Parts (1)	Maximum Temperature (2)
Walls, ceiling and floor of the test corner	175°C
Supply cables or cord*	175°C
Supplementary and reinforced insulation other than thermoplastic materials	1.5 times the values shown in IS 13450 (Part 1) : 1992 at -12.5°C

*For motor-operated equipment without heaters, these temperature measurements are not required.

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